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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,186	10/09/2001	David Reginald Adams	040283-0192	7541

7590

02/24/2003

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EXAMINER

BALASUBRAMANIAN, VENKATARAMAN

ART UNIT

PAPER NUMBER

1624

DATE MAILED: 02/24/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/890,186

Applicant(s)

ADAMS ET AL.

Examiner

Venkataraman Balasubramanian

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 December 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18, 21-25, 28-30, 32 and 34 is/are pending in the application.
- 4a) Of the above claim(s) 21-25, 28 and 30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18, 29, 32 and 34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Applicants' response, which included cancellation of, claims 19-20, 26-27, 31,33 and amendment to claim 1, filed on 12/6/2002, is made of record.

Applicants' response as to cancellation of claim 19-20, 26-27, 31, 33, is appears be an error as these claims were cancelled earlier by preliminary amendment. See paper # 5.

Claims 1-18, 21-25,28-30, 32 and 34 are in the case of which claims 21-25, and 28,30 were withdrawn from consideration. Claim 29 was examined as elected method of use. Claims 1-18, 32-34 were examined to the extent they embraced the elected subject matter.

Claims 1-18, 29 and 32-34 are active in the application.

As for applicants' argument about restriction requirement pertinent to method of use claims, as noted before the fact the instant compounds have more than one method of use by itself would negate unity of invention. Again the restriction is proper for reasons of record and the restriction had been made FINAL in the previous office action.

In view of applicants' response, the following rejections apply

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-18, 29, 32 and 34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject

matter which applicant regards as the invention. Following reasons apply. Any claim not specifically rejected is rejected as being dependent on a rejected claim.

1. The amended claim 1 now appears to be composition claim while all the dependent claims appear to recite claim as compound claim. If claim 1 is pharmaceutical composition claim then claim 32 would be a duplicate claim. It is not clear what is intended.
2. Claim 29, which appears to be the claim elected by the applicants as a specific method of treating specific disease, is indefinite as it depends on the non-elected claim 21 and lacks as such all the limitation. An appropriate correction is needed. Note this rejection is same as made in the previous office action.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) The invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8, 12-14, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Jonas et al. US 3,853,878 for reasons of record. To repeat:

Jonas et al. teaches several heaxahydropyrazino[1,2-a]indole compounds, which include those claimed herein. See compound of formula II on col. 1, line 50 and note the definition of R. See col. 2 for compounds made, See example 2. Hence it is held that in order to make compounds shown in example 2, Jonas et al. had inherently made the

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intermediates, which are claimed herein. Note In re Petering et al 133 USPQ 275; In Re Schaumann, 195 USPQ 5.

Applicants' argument to overcome this rejection is not persuasive. The fact that the compounds are intermediate and have no intended medical use no bearing on a 102 (b) rejection.

Claims 1-8, 12, and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Duggan et al. US 5,854,245.

In view of applicants' pointing out that the carboxyl or ester group is not permitted for instant R₆, this reaction is withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-8, 12-14, 16 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mokrosz et al., Med. Chem. Res. 3: 240-248, 1993 for reasons of record. To repeat:

Mokrosz et al. teaches rigid arylpiperazines as CNS agents, which include a compound with ethyl group on the piperazine ring. See compound 7 on page 241, and process of making on page 247.

While said compound doesn't anticipate the scope of instant claims in view of the proviso in claim 1, they are very closely related, having a methyl group on the phenyl ring vs. unsubstituted phenyl ring compound of the reference. However, compounds that differ only in having H vs Me are not deemed patentably distinct absent evidence of superior or unexpected properties. See for compounds that differ only as H vs Me in the phenyl ring, In re Wood 199 USPQ 137; In re Lohr 137 USPQ 548. Thus it would have been obvious to one skilled in the art at the time of the invention was made to expect instant compounds to possess the utility taught by the applied art in view of the close structural similarity outlined above.

Applicants' argument to overcome this rejection by showing comparative example is not persuasive.

The issue is would one trained in the art be motivated^{to}/make based on the unsubstituted arylpiperazine taught by Mokrosz et al., to make arylpiperazines with a methyl group in the aryl ring. The rejection is based on this fact and it would be obvious for one trained in the art make such compounds, as he would expect these compounds to possess the utility taught by Mokrosz et al.

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Thus the difference between the instant compound and the prior art compound is Methyl vs Hydrogen. Hence applicants' comparative showing halosubstituted compounds is not relevant.

Hence the rejection ^(p)proper and is maintained.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication from the examiner should be addressed to Venkataraman Balasubramanian (Bala) whose telephone number is (703) 305-1674. The examiner can normally be reached on Monday through Thursday from 8.00 AM to 6.00 PM. The Supervisory Patent Examiner (SPE) of the art unit 1624 is Mukund Shah whose telephone number is (703) 308-4716.

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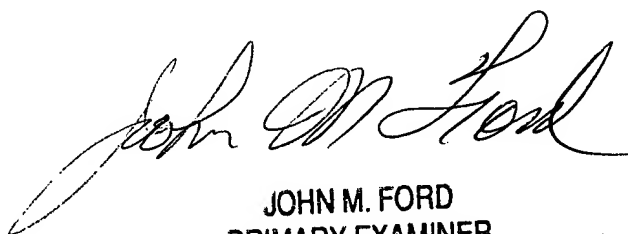
The fax phone number for the organization where this application or proceeding is assigned (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

W

V. Balasubramanian

2/22/2003



JOHN M. FORD
PRIMARY EXAMINER
GROUP - ART UNIT 1624